

### REMARKS

Claims 1-8 and 11-22 are pending in the above-identified application. A portion of claim 2, as well as claims 9 and 10, have been inserted into claim 1. Other changes to the claims primarily address matters of form.

#### Issues under 35 USC 112, second paragraph

Claims 13 has been rejected under 35 USC 112, second paragraph, as allegedly being indefinite. Claim 13 has been amended to remove the antecedent basis issue such that this rejection should now be withdrawn.

#### Issues under 35 USC 103(a)

Claims 1, 2, 4, 6, 7 and 12 have been rejected under 35 USC 103(a) as being unpatentable over Vishnoi '156 (US 6,348,156) in view of Hedrick '075 (US 7,514,075).

Claims 3 and 9 have been rejected under 35 USC 103(a) as being unpatentable over Vishnoi '156 in view of Hedrick '075 and further in view of O'Connor '327 (US 7,074,327).

Claim 5 has been rejected under 35 USC 103(a) as being unpatentable over Vishnoi '156 in view of Hedrick '075 and further in view of Komatsu '433 (US 5,976,433).

Claim 8 has been rejected under 35 USC 103(a) as being unpatentable over Vishnoi '156 in view of Hedrick '075 and further in view of Mendel-Hartvig '847 (US 7,018,847).

The bases for all of the above rejections under 35 USC 103(a) have been removed with the insertion of claim 10 into claim 1, since the combination of the features of claims 1 and 10 are not rejected above. Thus, it is requested that these rejections be withdrawn.

Claims 10 and 11 have been rejected under 35 USC 103(a) as being unpatentable over Vishnoi '156 in view of Hedrick '075 and Mendel-Hartvig '847 and further in view of Leader '864 (US 6,193,864).

Claims 13 and 14 have been rejected under 35 USC 103(a) as being unpatentable over Vishnoi '156 in view of Hedrick '075 and further in view of Leader '864.

These rejections should be withdrawn based on the reasons below.

*Present Invention and Its Advantages*

The present invention, as recited in the above claims, is directed to a fractionation device that both filters out higher molecular weight protein solutes and allows for detection of lower molecular weight protein solutes by increasing the concentration thereof in a filtrate sample. Present independent claims 1, 13 and 14 all recite a fractionation device which includes a roller type tube pump wherein a flow channel or tube forming a circuit is squeezed with a roller and a portion of an outer wall of a cartridge. This construction allows for the presently claimed fractionation device to be advantageously compact, stable, and easy to handle, since the flow channel or tube is less likely to be unfastened from the device while in use. Note, for example the discussion at paragraph [0047] at pages 29-30 of the specification. As explained below, the cited references fail to disclose these features.

*Distinctions over Cited References*

Leader '864 discloses at col. 8, lines 31-33 a "peristaltic roller pump which includes a roller **206** that massages [a]... pump tube **136**." The Office Action asserts that Leader '864 discloses a flow pump that is a tube with a rotating rotor and a roller installed in a rotating manner in the outer circumference of the rotor which corresponds to the flow pump provided with a rotating rotor, roller and squeezing member as in the device of the present invention. Leader '864 discloses a cartridge for analyzing blood wherein the device includes a roller pump. The roller pump is said to include a roller that massages the pump tube and applies areas of alternating greater and lesser pressure to the pump tube to generate peristaltic motion. However, the roller pump does not have a component corresponding to a squeezing member, such that it is completely unclear from the Leader '864 disclosure how peristaltic motion is generated even if the roller is rotated.

Leader '864, as well as other cited references, fails to disclose or suggest a flow pump with a rotating rotor and a roller which is provided with a squeezing member formed from a portion of the outer wall of cartridge as in the present invention. Additionally, Leader '864 fails to disclose the use of an outer wall of a cartridge as a squeezing member or disposing a tube on an outer wall of a squeezing member. Consequently, numerous and significant patentable

distinctions exist between the present invention and all of the cited references such that all of the above-noted rejections must be withdrawn.

Vishnoi '156 discloses a blood processing system which can accommodate a membrane blood separation device as noted at the bottom of column 6 thereof. Vishnoi '156 discloses at col. 8, lines 9-40 and in Figure 6 a fluid circuit 46 with a cassette 28, wherein "...fluid pressure comprises positive and negative pneumatic pressure [lines 15-16]." Though Vishnoi '156 discloses that, "Other types of fluid pressure can be used," there is no disclosure or suggestion as how to remove or replace the various depicted components, such as diaphragms 194 and 196, in order to arrive at a pump system that does not use positive and negative pneumatic pressure and that does not use the described components.

Vishnoi '156 fails to disclose or suggest the claimed fractionation device of the present invention which employs a flow pump with a rotating rotor and a roller which is provided with a squeezing member formed from a portion of the outer wall of cartridge as recited in the present claims. The Office Action fails to provide any evidence whatsoever that one skilled in the art would have any reasonable motivation to replace the disclosed pneumatic pump system of Vishnoi '156 with a roller pump system of Leader '864, or how such a device would be constructed, or how such a device would work. The Office Action fails to describe how the pneumatic pump system of Vishnoi '156 is modified to include the roller pump system of Leader '864 and still include components, such as diaphragms 194 and 196. Vishnoi '156 further fails to disclose or suggest the device of the present invention which produces a filtrate, and from that filtrate, a concentrated solution having a targeted solute concentration that is higher than the concentration in the filtrate. The mere optional existence of a filtering medium in Vishnoi '156 cannot perform all of these functions, since the only consequence of such a component is the production of a filtrate. Vishnoi '156 mentions nothing about increasing a solute concentration from a filtrate. Consequently, significant patentable distinctions exist between the fractionation device of the present invention and Vishnoi '156, such that the above rejections must be withdrawn.

The additional references cited in support of the obviousness rejections noted above fail to make up for the deficiencies of Leader '864 or Vishnoi '156 as noted immediately above. Consequently, there fails to be any sufficient basis for maintaining any of these rejections.

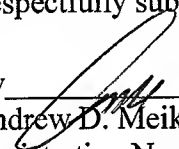
It is submitted for the reasons above that the present claims define patentable subject matter such that this application should now be placed in condition for allowance.

If any questions arise in the above matters, please contact Applicant's representative, Andrew D. Meikle (Reg. No. 32,868), in the Washington Metropolitan Area at the phone number listed below.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.17; particularly, extension of time fees.

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Respectfully submitted,

By   
Andrew D. Meikle  
Registration No.: 32,868  
BIRCH, STEWART, KOLASCH & BIRCH, LLP  
8110 Gatehouse Road  
Suite 100 East  
P.O. Box 747  
Falls Church, Virginia 22040-0747  
(703) 205-8000  
Attorney for Applicant